DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 18, 2009 has been entered.

2. This Office action is responsive to the amendments filed August 18, 2009. Claims 1, 40-45 and 47-53 are pending. Claim 1 has been amended. Claims 2-39, 46 and 54-56 have been cancelled.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on April 29, 2009 and May 8, 2009 were filed after the mailing date of the Final rejection on February 18, 2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. **Claims 1, 40-43 & 47-53** are rejected under 35 U.S.C. 103(a) as being unpatentable over McGukin, Jr. (US 6,280,450) in view of Tihon et al. (US 5,415,656), Kieturakis (US 5,794,626) and further in view of Burbank et al. (US 5,526,822).

McGukin, Jr. discloses a biopsy instrument for retrieving an entire tissue specimen containing a lesion from surrounding tissue at a target site within a patient's breast, having a longitudinal axis and a tissue penetrating distal tip 65 and comprising:

(a) an elongated shaft 20 having a longitudinal axis (see col. 6, lines 16-20);

(b) a tissue penetrating distal end 65 adapted for tissue penetration (see col. 6, lines 50-52); and,

(c) a distal shaft portion proximal to the distal end 65;

(d) an electrically powered cutting element (50, 55) longitudinally disposed on a distal shaft portion of the instrument, which is actuatable between a radially retracted position and a radially extended position, relative to the distal shaft portion, and which is movable in said radially extended position to isolate a desired intact issue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see col. 6, lines 23-26; col. 7, lines 30-38),

wherein the tissue cutting element (50, 55) is longitudinally disposed on the distal shaft portion;

wherein the tissue cutting element (50, 55) is configured to be rotated at least in part about the longitudinal axis in the radially extended position to isolate the tissue specimen (see figs. 1-5).

McGukin, Jr. discloses an instrument, as described above, that teaches all the limitations of the claims except for an electrosurgical cutting element, an automatically controllably sliding outer sheath, a first driving member to move the outer sheath, or a second driving member to axially move the elongated shaft.

However, **Kieturakis** teaches that it is known to provide tissue cutting elements 15 with one end secured to a distal shaft portion and another end, which is movable with respect to the distal shaft portion such that the tissue cutting elements are actuatable between a radially retracted position and a radially extended position by moving the one end movable with respect to the distal shaft portion toward the end secured to the distal shaft portion (see abstract; see figs. 2-3 & 5-8).

Moreover, **Tihon et al.** disclose an apparatus comprising an electrosurgical cutting wire 1, energized by radio frequency (RF) energy; wherein an electrical conductor 35 having a distal end electrically connected to the electrosurgical cutting element and a proximal end configured to be connected to a source ESU to deliver radio frequency energy from the source to the electrosurgical cutting element (see figs. 2 & 8; col. 1, lines 65-68; col. 2, lines 1-5 & 20-31; col. 3, lines 21-33; col. 5, lines 56-64; col. 8, lines 32-41).

Furthermore, **Burbank et al.** disclose a biopsy instrument for retrieving tissue specimen from surrounding tissue at a target site; wherein the instrument includes a first longitudinal driving member 64 in the housing secured to an outer sheath 268 is configured to axially move the outer sheath 268 between distal and proximal positions (see fig. 11A; col. 17, lines 31-37); wherein a second longitudinal driving member 64 in

the housing 14 secured to the proximal portion of an elongated shaft 44 configured to axially move the elongated shaft 44 (see figs. 1K, 2 & 4; col. 13, lines 18-19; col. 14, lines 2-8, 18-22 & 26-43; col. 16, lines 49-67; col. 17, lines 1-9).

In regards to **claims 1, 40-43, 47 & 49-53**, both McGukin, Jr. and Kieturakis teach biopsy instruments for retrieving body tissue (see respective abstracts); McGukin, Jr. further teaches a plurality of cauterizing cutting elements (see col. 5, lines 56-63; col. 6, lines 23-26), which are actuatable between a radially retracted position and a radially extended position (see col. 7, lines 30-38); Kieturakis teaches that that it is known to provide tissue cutting elements 15 with one end secured to a distal shaft portion and another end, which is movable with respect to the distal shaft portion such that the tissue cutting elements are actuatable between a radially retracted position and a radially extended position by moving the one end movable with respect to the distal shaft portion toward the end secured to the distal shaft portion (see abstract; see figs. 2-3 & 5-8); because the Examiner takes official notice that it is known that providing distal shaft portion for securing one end of the tissue cutting elements while the other end is movable with respect to the distal shaft portion achieves a biopsy instrument having an axially controlled distal portion, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of McGukin, Jr. with cutting elements having one end secured to a distal shaft portion and another end, which is movable with respect to a distal shaft portion as taught by Kieturakis in order to achieve a biopsy instrument having an axially controlled distal portion that facilitates tissue piercing.

Moreover, both McGukin, Jr. and Tihon et al. teach body excisional devices; McGukin, Jr. teaches cutting elements that are electrocauterizing (see col. 6, lines 23-25); since Tihon et al. teach an arrangement comprising a conductor for powering an electrosurgically powered cutter to excise a body tissue makes the cutting operation easier, more direct, and thus less traumatic, than cutting with an unpowered cutter (see col. 1, line 65 to col. 2, line 5), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of McGukin, Jr. as modified by Kieturakis above with an electrical conductor as taught by Tihon et al. in order to power the electrosurgical cutter so as to make the cutting operation easier, more direct and thus less traumatic, than cutting with an unpowered cutter. Moreover, use of RF powered cutting element permits the convenient application of coagulating power for hemostasis.

Both Kieturakis and Burbank et al. teach biopsy devices associated with a stereotactic apparatus for axially directing a needle tip into a lesion in the patient (see abstract, figure 10 & col. 6, lines 13-17; col. 7, lines 15-18 & 47-50; col. 8, lines 2-5 of Kieturakis; see figs. 1K, 2 & 4; col. 13, lines 18-19; col. 14, lines 2-8, 18-22 & 26-39; col. 16, lines 49-67; col. 17, lines 1-9 of Burbank et al.); since Burbank et al. also teach a second longitudinal driving member 64 mounted on the housing 14 for axially moving the elongated shaft 44 in order to fine tune the location of the tissue penetrating distal tip 45 of the shaft 44 (see col. 14, lines 2-8, 18-22 & 26-39), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the apparatus of McGukin as modified by Tihon et al. and Kieturakis with a second

longitudinal driver as taught by Burbank et al. in order to fine tune the location of the tissue penetrating distal tip of the shaft.

Moreover, since Kieturakis teaches an automated biopsy apparatus that includes an outer sheath that is slidably disposed about the shaft such that the outer sheath is configured to axially move between distal and proximal positions for selectively covering and uncovering the cutting element (see col. 9, lines 11-17), and Burbank et al. teach a mechanism for axially moving an outer sheath between distal and proximal locations (see fig. 11A; col. 17, lines 31-37), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the apparatus of McGukin as modified by Tihon et al. and Kieturakis above with an outer sheath and a driving member for axially moving the outer sheath as taught by Burbank et al. in order to automatically selectively cover and uncover the cutting element.

The Examiner notes that the instrument of McGukin, Jr. as modified by Tihon et al., Kieturakis and Burbank with respect to claims 1, 40-43, 47 & 49-53 above is fully capable of facilitating "placement of the distal end of the elongated electrosurqical cutting element distal to the tissue specimen and the proximal end of the elongated electrosurqical cutting element proximal to the tissue specimen so that rotation of the elongated electrosurgical cutting element severs the entire tissue specimen containing the lesion from surrounding tissue at a target site."

In regards to claim 48, Kieturakis discloses a biopsy instrument wherein the proximal driver unit 150 further controls axial movement of said shaft 40 (see col. 6, lines 13-19, 44-52, 56-62 & 66-67; col. 7, lines 1-4 & 31-36; col. 9, lines 11-17); since Kieturakis teaches an automated biopsy apparatus that includes an integrated proximal

driver unit 150 to automatically actuate the various actuation mechanisms of the biopsy apparatus in preprogrammed cycles (see col. 7, lines 31-37), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the apparatus of McGukin as modified by Tihon et al., Kieturakis, and Burbank et al. above with a proximal driver unit that controls axial movement of the shaft and sheath as taught by Kieturakis in order to permit the controller to automatically actuate the various actuation mechanisms in preprogrammed cycles including axial shaft movement and covering/uncovering of the cutting element.

6. **Claims 44-45** are rejected under 35 U.S.C. 103(a) as being unpatentable over McGukin, Jr. (‘450) in view of Tihon et al. (‘656), Kieturakis (‘626) and further in view of Burbank et al. (‘822) and further in view of Salim et al. (WO 95/02370).

McGukin, Jr. as modified by Tihon et al., Kieturakis and Burbank et al. discloses a system, as described above, that teaches all the limitations of claims 44-45 except for a bipolar or monopolar electrode.

However, **Salim et al.** teach a biopsy instrument for retrieving an entire tissue specimen containing a lesion from surrounding tissue at a target site within a patient’s breast, having a longitudinal axis and a tissue penetrating distal tip 2 and comprising:

(a) an elongated shaft 5 having a longitudinal axis (see fig. 1);

(b) a tissue penetrating distal end 2 adapted for tissue penetration (see pg. 11, lines 12-17); and,

(c) a distal shaft portion proximal to the distal end 2 (see fig. 1);

(d) at least one electrically powered cutting element 3 longitudinally disposed on a distal shaft portion of the instrument, which is actuatable between a radially retracted position and a radially extended position, relative to the distal shaft portion, and which is movable in said radially extended position to isolate a desired intact issue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see abstract and fig. 1),

wherein the at least one tissue cutting element 3 is longitudinally disposed on the distal shaft portion;

wherein the at least one tissue cutting element 3 is configured to be rotated at least in part about the longitudinal axis in the radially extended position to isolate the tissue specimen (see fig. 1);

wherein the at least one tissue cutting element 3 has one end secured to a distal shaft portion and another end, which is movable with respect to the distal shaft portion such that the tissue cutting elements 3 are actuatable between a radially retracted position and a radially extended position by moving the one end movable with respect to the distal shaft portion toward the end secured to the distal shaft portion (see abstract and fig. 1); wherein the cutting element 3 may be bipolar or monopolar (see pg. 3, lines 1-2).

Because the Examiner takes official notice that it is known to provide a bipolar electrode for tissue cutting in order to localize the cauterization to a small predefined volume of tissue, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of McGukin, Jr. as modified by

Tihon et al., Kieturakis and Burbank et al. with a bipolar electrode cutting element as taught by Salim et al. in order to localize the cauterization to a small predefined volume of tissue.

Similarly, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of McGukin, Jr. as modified by Tihon et al., Kieturakis and Burbank et al. with a monopolar electrode as taught by Salim et al. in order to cauterize an undefined volume of tissue.

7. **Claims 1, 40-45, and 47-53** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis (US 5,794,626) in view of Salim et al. (WO 95/02370), Tihon et al. (US 5,415,656), and further in view of Burbank et al. (US 5,526,822).

- ***Regarding claims 1, 40-43 & 47-53 (general content of the prior art):***

In regards to **claim 1**, Kieturakis discloses a biopsy instrument 5 for retrieving tissue specimen from surrounding tissue at a target site, having a longitudinal axis and tissue penetrating distal tip 45, comprising:

a housing;

an elongated shaft 40 having a longitudinal axis and a proximal end within the housing (see figs. 3-4); and

an elongated cutting element 15 disposed on a distal portion of the instrument, which is actuatable between a radially retracted position and a radially extended position and which is rotationally movable in said radially extended position to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see abstract; see figs. 3 & 5-8);

an outer sheath (not shown) slidably disposed about the shaft and configured for axial movement between distal and proximal positions for selectively covering and uncovering the cutting element (see column 9/lines 11-17);

a rotating driving member in the housing connected to the proximal portion of the elongated shaft 40 to rotate the shaft 40 with respect to the housing and to rotate the elongated cutting element 15 secured to the distal portion of the shaft 40 (see column 6/lines 44-62); and

a longitudinal driving member 30 (see column 4/line 59 to column 5/line 2) slidably disposed within the outer sheath having a proximal portion in the housing and a distal portion connected to the elongated electrosurgical cutting element to actuate the cutting element between the radially retracted position and the radially extended position (see figs. 1-3; col. 3, lines 61-67; col. 6, lines 13-19; col. 9, lines 11-17).

In regards to **claim 42**, Kieturakis discloses a biopsy instrument wherein the cutting element 15 has a proximal end 23 and a distal end 24 and which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended position (see fig. 2).

In regards to **claim 43**, Kieturakis discloses a biopsy instrument wherein the cutting element 15 is configured so that the distal end 24 is fixed and the proximal end 23 moves toward the distal end 24 in order to radial extend the cutting element 15 (see figs. 2-3).

In regards to **claim 47**, Kieturakis discloses a biopsy instrument including a proximal driver unit 150 for controlling radial expansion and retraction of the cutting

element and rotation of the cutting element about the longitudinal axis (see col. 6, lines 13-19, 44-52, 56-62 & 66-67; col. 7, lines 1-4 & 31-36; col. 8, lines 2-10).

In regards to **claim 49**, Kieturakis discloses a biopsy instrument wherein the cutting element 15 is configured to be manipulated to segment the tissue specimen (see figs. 2-3; col. 3, lines 61-67).

In regards to **claim 50**, Kieturakis discloses a biopsy instrument wherein the electrosurgical proximal tissue cutting element 15 is configured to segment the tissue specimen after it has been isolated from the surrounding tissue (see figs. 2-3; col. 3, lines 61-67).

In regards to **claim 51**, Kieturakis discloses a biopsy instrument wherein the tissue cutting element 15 is capable of segmenting the tissue specimen as it is being retracted from said radially extended position to said radially retracted position (see figs. 2-3).

In regards to **claim 52**, Kieturakis discloses a biopsy instrument wherein the radially extended position comprises a first radially extended position, and wherein the cutting element 15 is further actuatable to a plurality of additional radially extended positions and rotatable about the longitudinal axis in each of said radially extended positions to selectively peripherally segment said tissue specimen (see figs. 2-3).

In regards to **claim 53**, Kieturakis discloses a biopsy instrument wherein the instrument further comprises a cannula 10 having a lumen 56 for providing a passageway into the patient's body; the segments of the tissue specimen being removable from the patient's body through the cannula 10 (see fig. 3).

Kieturakis discloses an instrument, as described above, that fails to expressly teach an electrosurgical cutting element, an automatically controllably sliding outer sheath, a first driving member to move the move the outer sheath, or a second driving member to axially move the elongated shaft.

However, **Salim et al.** teach a biopsy instrument for retrieving an entire tissue specimen containing a lesion from surrounding tissue at a target site within a patient's breast, having a longitudinal axis and a tissue penetrating distal tip 2 and comprising:

(a) an elongated shaft 5 having a longitudinal axis (see fig. 1);

(b) a tissue penetrating distal end 2 adapted for tissue penetration (see pg. 11, lines 12-17); and,

(c) a distal shaft portion proximal to the distal end 2 (see fig. 1);

(d) at least one electrically powered cutting element 3 longitudinally disposed on a distal shaft portion of the instrument, which is actuatable between a radially retracted position and a radially extended position, relative to the distal shaft portion, and which is movable in said radially extended position to isolate a desired intact issue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see abstract and fig. 1),

wherein the at least one tissue cutting element 3 is longitudinally disposed on the distal shaft portion;

wherein the at least one tissue cutting element 3 is configured to be rotated at least in part about the longitudinal axis in the radially extended position to isolate the tissue specimen (see fig. 1);

wherein the at least one tissue cutting element 3 has one end secured to a distal shaft portion and another end, which is movable with respect to the distal shaft portion such that the tissue cutting elements 3 are actuatable between a radially retracted position and a radially extended position by moving the one end movable with respect to the distal shaft portion toward the end secured to the distal shaft portion (see abstract and fig. 1); wherein the cutting element 3 may be bipolar or monopolar (see pg. 3, lines 1-2).

Moreover, **Tihon et al.** disclose an apparatus comprising an electrosurgical cutting wire 1, energized by radio frequency (RF) energy; wherein an electrical conductor 35 having a distal end electrically connected to the electrosurgical cutting element and a proximal end configured to be connected to a source ESU to deliver radio frequency energy from the source to the electrosurgical cutting element (see figs. 2 & 8; col. 1, lines 65-68; col. 2, lines 1-5 & 20-31; col. 3, lines 21-33; col. 5, lines 56-64; col. 8, lines 32-41).

Furthermore, **Burbank et al.** disclose a biopsy instrument for retrieving tissue specimen from surrounding tissue at a target site; wherein the instrument includes a first longitudinal driving member 64 in the housing secured to an outer sheath 268 is configured to axially move the outer sheath 268 between distal and proximal positions (see fig. 11A; col. 17, lines 31-37); wherein a second longitudinal driving member 64 in the housing 14 secured to the proximal portion of an elongated shaft 44 configured to axially move the elongated shaft 44 (see figs. 1K, 2 & 4; col. 13, lines 18-19; col. 14, lines 2-8, 18-22 & 26-43; col. 16, lines 49-67; col. 17, lines 1-9).

- ***In regards to claims 1, 40-43, 47 & 49-53 (motivation to combine):***

Both Kieturakis and Salim et al. teach biopsy instruments having at least one radially expandable and retractable biopsy element, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Kieturakis with at least one electrically cutting element as taught by Salim et al. in order to facilitate excision and coagulation the cut tissue (see pg. 4, lines 1-4 of Salim et al.).

Similarly, since both Kieturakis and Tihon et al. teach radially expandable and retractable cutting elements associated with medical devices for cutting tissue, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Kieturakis as modified by Salim et al. with an electrosurgical cutting element as taught by Tihon et al. that is movable in said radially extended position at least 360 degrees about the longitudinal axis to isolate a desired intact issue specimen in order to make the cutting operation easier, more direct and thus less traumatic, than cutting with an unpowered cutter. Moreover, use of RF powered cutting element permits the convenient application of coagulating power for hemostasis (see Tihon et al., column 1/line 65 to column 2/line 5).

Both Kieturakis and Burbank et al. teach biopsy devices associated with a stereotactic apparatus for axially directing a needle tip into a lesion in the patient (see abstract, figure 10 & col. 6, lines 13-17; col. 7, lines 15-18 & 47-50; col. 8, lines 2-5 of Kieturakis; see figs. 1K, 2 & 4; col. 13, lines 18-19; col. 14, lines 2-8, 18-22 & 26-39; col. 16, lines 49-67; col. 17, lines 1-9 of Burbank et al.); since Burbank et al. also teach a

second longitudinal driving member 64 mounted on the housing 14 for axially moving the elongated shaft 44 in order to fine tune the location of the tissue penetrating distal tip 45 of the shaft 44 (see col. 14, lines 2-8, 18-22 & 26-39), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the apparatus of Kieturakis as modified by Salim et al. as modified by Tihon et al. above with a second longitudinal driver as taught by Burbank et al. in order to fine tune the location of the tissue penetrating distal tip of the shaft.

Moreover, since Kieturakis teaches an automated biopsy apparatus that includes an outer sheath that is slidably disposed about the shaft such that the outer sheath is configured to axially move between distal and proximal positions for selectively covering and uncovering the cutting element (see col. 9, lines 11-17), and Burbank et al. teach a mechanism for axially moving an outer sheath between distal and proximal locations (see fig. 11A; col. 17, lines 31-37), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the apparatus of Kieturakis as modified by Salim et al. and Tihon et al. above with a driving member for axially moving the outer sheath as taught by Burbank et al. in order to automatically selectively cover and uncover the cutting element. Moreover, it has previously been held that merely making automatic is not patentable--See *In re Venner, 262 F.2d 91, 95, 120 USPQ 192, 194 (CCPA 1958).*

The Examiner notes that the instrument of Kieturakis as modified by Salim et al., Tihon et al. and Burbank with respect to claims 1, 40-43, 47 & 49-53 above is fully capable of facilitating "placement of the distal end of the elongated electrosurqical cutting element distal to the tissue

specimen and the proximal end of the elongated electrosurqical cutting element proximal to the tissue specimen so that rotation of the elongated electrosurgical cutting element severs the entire tissue specimen containing the lesion from surrounding tissue at a target site."

- ***In regards to claim 48 (motivation to combine):***

Kieturakis discloses a biopsy instrument wherein the proximal driver unit 150 further controls axial movement of said shaft 40 (see col. 6, lines 13-19, 44-52, 56-62 & 66-67; col. 7, lines 1-4 & 31-36; col. 9, lines 11-17); since Kieturakis teaches an automated biopsy apparatus that includes an integrated proximal driver unit 150 to automatically actuate the various actuation mechanisms of the biopsy apparatus in preprogrammed cycles (see col. 7, lines 31-37), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the apparatus of Kieturakis as modified by Salim et al., Tihon et al. and Burbank et al. above with a proximal driver unit that controls axial movement of the shaft and sheath as claimed in order to permit the controller to automatically actuate the various actuation mechanisms in preprogrammed cycles including axial shaft movement and covering/uncovering of the cutting element.

- ***In regards to claims 44-45 (motivation to combine):***

Because the Examiner takes official notice that it is known to provide a bipolar electrode for tissue cutting in order to localize the cauterization to a small predefined volume of tissue, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Kieturakis as modified by Salim et al., Tihon et al. and Burbank et al. with a bipolar electrode cutting element as

taught by Salim et al. in order to localize the cauterization to a small predefined volume of tissue.

Similarly, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Kieturakis as modified by Salim et al., Tihon et al. and Burbank et al. with a monopolar electrode as taught by Salim et al. in order to cauterize an undefined volume of tissue.

Response to Arguments

8. Applicant's arguments filed June 16, 2009 have been fully considered but they are not persuasive. Applicant contends that none of the applied prior art references teach a device that ensures that the entire lesion is removed. This argument has been considered but has not been deemed persuasive.

In response to the Applicant's argument, the Examiner respectfully traverses. For example, according to the MPEP, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the devices of Kieturakis and Salim et al. are fully capable of removing an entire lesion by first cutting a peripheral margin around the lesion (i.e. also known as coring the lesion). Furthermore, said devices are also fully capable of facilitating "placement of the distal end of the elongated electrosurqical cutting element distal to the tissue specimen and the proximal end of the elongated electrosurqical cutting element proximal to the tissue specimen so that rotation of the elongated electrosurgical cutting

element severs the entire tissue specimen containing the lesion from surrounding tissue at a target site" in the same manner. Moreover, total removal of the lesion does not necessarily mean removal of the entire intact lesion. As such, whether the devices subsequently cut the tissue lesion piece-by-piece, is irrelevant as long as the lesion is completely removed.

In view of the foregoing, the rejections over Kieturakis are maintained.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 2:00PM-10:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. T./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736